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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,386	04/21/2008	Brian Barney	TEVE-125US	2232
23122 RATNERPRES	7590 01/05/201 STLA	2	EXAM	IINER
P.O. BOX 980 VALLEY FORGE, PA 19482		VASAT, PETER S		
			ART UNIT	PAPER NUMBER
			3764	
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			01/05/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.	Applicant(s)	
10/574,386	BARNEY ET AL.	
Examiner	Art Unit	
PETER S. VASAT	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS.

WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed

after SIX (6) MONTHS from the mailing date of this communication.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any

earned patent term adjustment. See 37 CFR 1.704(b).

Status	
1)🛛	Responsive to communication(s) filed on 19 October 2011.
2a)	This action is FINAL . 2b) ☑ This action is non-final.
3)	An election was made by the applicant in response to a restriction requirement set forth during the interview or
	; the restriction requirement and election have been incorporated into this action.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is

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	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
positi	on of Claims		
	Claim(s) 1-3.30 and 31 is/are pending in the application.		
	5a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed.		
	Claim(s) <u>1-3.30 and 31</u> is/are rejected. Claim(s) is/are objected to.		
	Claim(s) are subject to restriction and/or election requirement.		
olicati	on Papers		
0) ☐ The specification is objected to by the Examiner. 1) ☒ The drawing(s) filed on 31 March 2006 [st/arc: a) ☐ accepted or b) ☒ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 2) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
ority u	inder 35 U.S.C. § 119		
	Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). ☑ All b) □ Some * c) □ None of: Ⅰ ☑ Certified cooles of the priority documents have been received		

Pri

a)🛛 All	b) ☐ Some * c) ☐ None of:
1.🛛	Certified copies of the priority documents have been received.
2.	Certified copies of the priority documents have been received in Application No
3.	Copies of the certified copies of the priority documents have been received in this National Stage
	application from the International Bureau (PCT Bule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

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Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413)	
Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date	
3) X Information Disclosure Statement(s) (PTO/SB/06)	5). Notice of Informal Pater LApplication.	
Paper No(s)/Mail Date 9/27/2011.	6) Other:	

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DETAILED ACTION

Election/Restrictions

- Applicant's election with traverse of the invention of Figure 3 in the reply filed on 10/19/2011 is acknowledged. The traversal is on the ground(s) that:
 - a. In Cocozza, the cup 120 is not "held" adjacent the reservoir by another object. Cocozza's cup 120 is freely rotatable via knob 112. Because Cocozza's cup 120 is not "held" by another object, it follows that the cup 120 is not "released" by another object. Thus, claim 1 recites features that are neither disclosed nor suggested by Cocozza. Because Cocozza does not anticipate sole independent claim 1, there exists a technical relationship among the inventions.
- 2. This is not found persuasive because Cocozza's cup 120 which is part of the conveyor 122 is held in place adjacent to the reservoir by the intermediate disc 103 (fig. 10; col. 8, II. 41-43). Additionally, Cocozza's cup is not freely rotatable via knob 112, because when the cup 120 is in the dispensing position, the lug 132 of the mechanism 112 is against step 134, which acts as a limiting stop (col. 8-9, II. 67-1). Simultaneously, the tongues 113 of the free release device act against the steps 117 (col. 9, II. 2-4). Thus it is not possible to further rotate the knob 112 anticlockwise, whereas it can be rotated in the opposite direction, the free release device enabling the shaft 114 and hence the conveyor 122 to be dragged in the same direction of rotation (clockwise), until the device 120 has been returned to the filling commencement position of FIG. 11 (col. 9, II. 4-10). Cocozza's disclosure explicitly states that the cup 120 can only be "dragged" along with the conveyor 122 to return to the filling commencement position.

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3. Therefore, requirement is still deemed proper and is therefore made FINAL.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, all of the features of claim 31 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filling date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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a.

Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In re claim 1, Cocozza's inhaler 2 comprises a reservoir 124 for powdered

- Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Cocozza (US 5033463).
 - medicament and a mouthpiece 180 for user inhalation of a predetermined dose of medicament (fig. 10; col. 2, II. 46-52; col. 10, II. 8-16). Cocozza's inhaler 2 further comprises a delivery channel 152 between a discharge outlet of the reservoir 124 and the mouthpiece 180 (fig. 10). Cocozza's inhaler 2 further comprises a device 120 and 122 (cup and disc conveyor) held adjacent the reservoir 124 for receiving the predetermined dose of medicament from the discharge outlet of the reservoir 124 and transferring it to the delivery channel 152 (col. 9, II. 31-36). Cocozza's inhaler 2 further comprises a mechanism 112 (knob 112 rotates shaft 114 between a filling position and a dispensing position) adapted to release the device 120 and 122, and permit controlled movement thereof to the delivery channel for delivery of the medicament (fig. 10-11; col. 8-9, II. 36-10). Furthermore, when the device 120 is in the dispensing position, the lug 132 of the mechanism 112 is against step 134, which acts as a limiting stop

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(col. 8-9, Il. 67-1). Simultaneously, the tongues 113 of the free release device act against the steps 117 (col. 9, Il. 2-4). Thus it is not possible to further rotate the knob 112 anticlockwise, whereas it can be rotated in the opposite direction, the free release device enabling the shaft 114 and hence the device 122 to be dragged in the same direction of rotation (clockwise), until the device 120 has been returned to the filling commencement position of FIG. 11 (col. 9, Il. 4-10).

- b. In re claim 2, Cocozza discloses a cup 120 for receiving the medicament (fig. 10; col. 8, II. 36-66) and a longitudinally slidable body 106 mounting the cup 120 when the slidable body 106 is in the longitudinally downward position (col. 9, II. 37-66). Cocozza further discloses an abutment means 150 that is movable to release the device for movement to the delivery channel 152 (col. 9, II. 37-66).
- c. In re claim 3, Cocozza further discloses actuation means 138 (dispensing knob), which upon being pressed causes abutment means 150 to move downward (col. 9, II, 51-56).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cocozza
 (US 5033463) in view of Bougamont (US 5239992).
 - d. In re claim 30, Cocozza discloses the invention as discussed above in claim 3, but does not disclose a breath actuable apparatus. Bougamont teaches a powder inhaler that features a breath actuable apparatus (col. 1, 19-65). Bougamont's inhaler permits an effective inhalation of powder medicament by making the distribution of each charge of powder dependent on the inhalation movement of the patient (col. 1, II. 62-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Cocozza with the breath actuable apparatus taught by Bougamont to provide a powder inhaler that permits an effective inhalation of powder medicament by making the distribution of each charge of powder dependent on the inhalation movement of the patient.
- Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cocozza (US 5033463) in view of Bougamont (US 5239992), and further in view of Zanen (US 5429122).

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In re claim 31, Cocozza in view of Bougamont disclose the invention as discussed above in claim 30, but they do not disclose that the mechanism is between opposed spaced walls of the reservoir and has a member which is retractable on a user taking a breath on the mouthpiece. Zanen teaches a powder inhaler 1 having a mechanism 11 between opposed spaced walls of the reservoir 3 that is retractable (from the position shown in figure 1 to the position shown in figure 2) on a user taking a breath on the mouthpiece (fig. 1, 2; col. 3, II. 35-67). Zanen further teaches that the inhaler can be used to administer several doses (col. 1, II, 15-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Cocozza in view of Bougamont with the retractable mechanism between opposed spaced walls of the reservoir. as taught by Zanen, to provide an inhaler that can be used to administer several doses and permits an effective inhalation of powder medicament by making the distribution of each charge of powder dependent on the inhalation movement of the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER S. VASAT whose telephone number is (571)270-7625. The examiner can normally be reached on Monday - Thursday, 8:00AM - 6:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on (571)272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PETER S. VASAT/ Examiner, Art Unit 3764

/LoAn H. Thanh/ Supervisory Patent Examiner, Art Unit 3764